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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,314	11/18/2003	John M. Stewart	P26,473-A USA	7296

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SYNNESTVEDT & LECHNER, LLP
1101 MARKET STREET
26TH FLOOR
PHILADELPHIA, PA 19107-2950

EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,314	STEWART ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/2007 has been entered.

Examiner acknowledges changes to the Sequence Listings submitted on 8/6/2007.

Further, Examiner acknowledges communication with Mr. Kelly on 8/28/2007 in regards to claim 23. Examiner would like to thank Mr. Kelly for the fast response to the examiner's inquiry in regards to potential amendments to the instant claim 23. Examiner considered the potential amendments to claim 23, but unfortunately did not find claim 23 allowable as to the matters presented, and thus the rejection below follows.

Status of Claims

Claims 23, 24, 32 and 34 are pending and under consideration, as amended by the examiner on 4/11/2007.

Priority

This application claims priority to 60/427,682 filed on 11/18/2002.

Drawings

The Drawings submitted on 11/18/2003 are accepted and approved.

Objections

37 CFR 1.57(d) states that incorporation by reference by hyperlink or other form of browser executable code is not permitted. Examples of a hyperlink or a browser-executable code are a URL placed between these symbols "< >" and http:// followed by a URL address. Please amend the pages to correct site the web page10, lines 9 and 10, for example.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from *Enzo Biochemical* (see above).

In the instant case, the Applicants refer to a broad genus of variants of SEQ ID NO:2. The structures of the genus that are claimed are not sufficiently described because Applicants did not provide in the instant specification or claims any specific fragments of SEQ ID NO:2 that would correspond to different variants of SEQ ID NO:2.

Thus, one skilled in the art would be unable to determine, according to claim 23, what is the structure of these specific fragments that retain paralytic activity of SEQ ID NO:2 and thus what is the function of these undefined fragments. Further, claim 23 uses an open language and thus the peptide used in the method can encompass any fragment of SEQ ID NO:2, even a single amino acid of SEQ ID NO:2, since the length of the fragment in the peptide as claimed is not defined. Moreover, since the structure of these different fragments of SEQ ID NO:2 is not disclosed, thus the function of these peptides cannot be ascertained. Thus, the written description requirement is not satisfied because the structure of these fragments does not correspond with their function.

Claims 23, 24, 32, and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length of the peptide of SEQ ID NO:2, does not reasonably provide enablement for fragments of SEQ ID NO:2. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In *re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

1) The nature of the invention: the instant invention refers to a method of providing analgesia or neuromuscular blocking comprising administering a peptide that contains a fragment of SEQ ID NO:2 wherein the peptide has paralytic activity.

2) The breadth of the claims: the claims are extremely broad because they encompass any peptide that contains a fragment of SEQ ID NO:2 that has paralytic activity and is administered to a mammal.

3) The predictability or unpredictability of the art: there is a great unpredictability in the art with regards to different variants of a peptide that has fragment of SEQ ID NO:2. Applicants on page 7, line 26 to page 8, line 6, describe different fragments of SEQ ID NO:2 that are significant for paralytic activity. However, no experiments or working examples are presented in the specification that would exemplify those fragments (for example at least 10 amino acids of SEQ ID NO:2, would work for it intended purpose i.e. a paralytic activity). Thus, one skilled in the art would not know whether a fragment of at least 10 amino acids would actually work when administered to a mammal.

4) & 5) The amount of direction or guidance presented:/The presence or absence of working examples: there are no working examples in regards to SEQ ID NO:2 or any

fragments of SEQ ID NO:2, that are depicted in the working examples. Therefore, specification, except describing relevant fragments on pages 7-8 of the specification, does not guide one skilled in the art what fragments work as to their paralytic activity and what fragments do not work, since no working examples are presented.

6) The quantity of experimentation necessary: there is a large quantity of experimentation necessary to determine which fragments of SEQ ID NO:2 when included in a peptide composition will retain the paralytic activity since no working examples are presented.

7) The state of the prior art: the shrew toxin was isolated and purified and was administered to a mammal.

8.) Level of skill in the art: the level of skill in this art is high.

There would be an undue experimentation to one skilled in the art to practice this invention when considering the totality of the wands factors. Therefore, Applicants are enabled for the full length of SEQ ID NO:2 but are not enabled for different fragments of SEQ ID NO:2 that retain paralytic activity, since no support can be found in the working examples considering fragments of SEQ ID NO:2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 24, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bucherl et al., (Venomous Animals and Their Venoms, Vol. 1, Academic Press, 1968).

On page 45, last paragraph, Bucherl et al. teach that the purified toxin was concentrated and with regards to mammals (i.e. rabbits), the lethal dose was determined. (See also Figure 2, on page 47). This toxin inherently includes the protein sequence of SE QID NO:2 of the instant claims because the proteins originates from the same source and has the same function.

Further, on page 46, third paragraph from the bottom, the effects of the venom of Blarina are discussed regarding changes in circulatory and respiratory systems of rabbits.

On page 48, second paragraph from the bottom, the effect of the venoms of shrews on experimental animals is discussed, such as paralysis of hind limbs and convulsions, where the intensity of reaction depended on the size of the dose and the site of administration, where the most effective were the intravenous injections of extract of the submilary glands of Blarina.

Claim 23 is anticipated by Bucherl et al. who discuss the shrew toxin being administered to rabbits to affect the paralysis. The instant claim 23, refers to a method of providing analgesia or neuromuscular blocking in a mammal comprising administration of a peptide that contains a fragment of SEQ ID NO:2 where the peptide has paralytic activity. Thus, claim 23 is anticipated by the prior art because a fragment

of SEQ ID NO:2 would be inherently present in the paralytic toxin from shrew that was discussed in Bucherl et al.

Also, claims 24 and 32 would be included in this rejection because analgesia or neuromuscular blocking are intended uses (claim 24) and the wild type peptide is the same as a synthetic peptide (claim 32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bucherl et al., (Venomous Animals and Their Venoms, Vol. 1, Academic Press, 1968) in view of Kohane et al.(U.S. 6,326,020).

The teachings of Bucherl et al. are discussed above where they do not teach a method of dosing a mammal in pain.

Kohane et al. teach different nerve blockers that were used in animal models to make animals insensitive to pain. (See for example, column 6, lines 29-46 and claim 17 in column 23).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method where the paralytic peptide as taught by

Bucherl et al. is administered to a mammal to alleviate pain as taught by Kohane et al. Further, the outcome would be predictable from the data of Bucherl et al.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

KATHLEEN KERR BRAGDON, PH.D.
SUPERVISORY PATENT EXAMINER